

**DIVISION OF HEALTH PLANNING  
AND RESOURCE DEVELOPMENT  
FEBRUARY 2005**

**CON REVIEW MU-NIS-1204-050  
GRENADA DIAGNOSTIC RADIOLOGY, LLC  
ESTABLISHMENT OF MOBILE POSITRON EMISSION  
TOMOGRAPHY (PET) SERVICES  
CAPITAL EXPENDITURE: \$16,541.32  
LOCATION: GRENADA, MISSISSIPPI**

**STAFF ANALYSIS**

**I. PROJECT SUMMARY**

**A. Applicant Information**

Grenada Diagnostic Radiology, LLC (GDR) is a closely held, member-managed limited liability company set in the State of Mississippi. The company is governed by a twelve-member board. Dr. Ralph C. Armstrong is the managing member.

The name and address of the registered agent and registered office is as follows:

Richard Reid, M.D.  
1332 Sunset Drive  
Grenada, Mississippi 38901

Grenada Diagnostic Radiology, LLC does not have existing obligations to provide uncompensated care or community service. Nevertheless, GDR will provide PET services at reduced fees or at no charge for persons who are unable to pay. GDR will participate in the Medicaid and Medicare programs to the extent allowed by those programs. Currently, GDR is a Medicare provider.

**B. Project Description**

Grenada Diagnostic Radiology, LLC (GDR) requests Certificate of Need (CON) authority to establish mobile positron emission tomography (PET) services at its facility one day per month for ten (10) hours each day. This schedule may be adjusted depending on the demand for service. Grenada Diagnostic Radiology, LLC will contract with Insight Health Corporation (Insight) to provide mobile PET services. This contract has not been finalized as it is contingent upon the granting of a Certificate of Need for this application. The mobile PET unit will be a GE Advance Nxi PET scanner (Insight system number G1258A) housed in a mobile trailer. The trailer will park in the parking lot adjacent to GDR's location at 1300 Sunset Drive, Grenada. Construction for the proposed project will include installing a concrete pad on which the trailer will sit. The site is already equipped for the provision of electrical and telephone service for the trailer. The expense for preparing the site for the mobile PET trailer will be borne by GDR. The applicant asserts that the project will allow GDR to offer its service to the community at little additional expense.

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According to the applicant, GDR offers the following services in the facility:

- Full-time CT Scanning
- Ultrasound
- Mammography
- Nuclear Medicine
- Routine X-ray Services

The total proposed capital expenditure is \$16,541.42 which is composed of the following: new construction cost - 59.72 percent, and site preparation cost - 40.28 percent. The applicant proposes to finance the proposed project from accumulated cash reserves of Grenada Diagnostic Radiology, LLC.

The applicant anticipates the obligation of the capital expenditure on this project within 60 to 90 days of CON approval. Services will begin as soon as the site for the mobile trailer is completed.

## **II. TYPE OF REVIEW REQUIRED**

The Mississippi State Department of Health reviews applications for the establishment of positron emission tomography services in accordance with Section 41-7-191, subparagraph (1)(d)(xv) and (j) Mississippi Code of 1972, Annotated, as amended, and duly adopted rules, procedures, plans, criteria, and standards of the Mississippi State Department of Health.

In accordance with Section 41-7-197 (2) of the Mississippi Code 1972 Annotated, as amended, any affected person may request a public hearing on this project within 20 days of publication of the staff analysis. The opportunity to request a hearing expires on March 7, 2005.

## **III. CONFORMANCE WITH THE STATE HEALTH PLAN AND OTHER ADOPTED CRITERIA AND STANDARDS**

### **A. State Health Plan (SHP)**

The **FY 2005 State Health Plan** addresses policy statements, criteria and standards which an applicant is required to meet before receiving CON authority to provide positron emission tomography services. The application submitted by Grenada Diagnostic Radiology, LLC is in substantial compliance with applicable policy statements and criteria and standards contained in the **FY 2005 State Health Plan**.

#### **SHP Policy Statements (PS) Regarding PET Services**

##### **PS-2 Indigent/Charity Care**

The applicant states that it will provide a "reasonable" amount of indigent/charity care.

##### **PS-5 Access to Supplies**

GDR asserts that the facility will have appropriate access to radio-pharmaceuticals.

##### **PS-6 Services and Medical Specialties Required**

According to Grenada Diagnostic Radiology, LLC, all required services and medical specialties are available at GDR, in the Grenada Medical Complex, or will be provided and are available at Grenada Medical Center in Grenada.

**PS-8 CON Approval**

GDR proposes to provide mobile PET services through the utilization of an existing mobile PET scanner unit (Insight Health Corporation). This equipment will provide services to a mobile route that will also include other hospitals.

**PS-13 Certification**

GDR will utilize a mobile PET vendor for the provision of PET services. GDR is applying for a CON through the Mississippi State Department of Health to offer mobile PET scanner services. According to GDR, Insight Health Corporation currently has two positron emission tomography scanner units operating in Mississippi. Insight Health Corporation will use unit G1258A to provide services at GDR. Both Insight units are CON approved under CONs #R-0494 and #R-0495.

**SHP Criterion 1 - Need**

The Certificate of Need criteria and standards for the acquisition or otherwise control of a positron emission tomography (PET) scanner and related equipment outlined in the **FY 2005 Mississippi State Health Plan** states that an entity desiring to acquire or to otherwise control the PET scanner must project a minimum of 750 clinical procedures per year, and must document a minimum population base of 300,000 per PET scanner unit.

Currently, there are three providers of mobile PET services in GDR's service area, General Hospital Service Area 1. Grenada Diagnostic Radiology, LLC proposes to join a mobile PET route operated by Insight Health Corporation which is already providing approved PET services in Mississippi. Therefore, the need criterion is already met.

Table 1 below gives the location and number of PET procedures performed in General Hospital Service Area 1 for fiscal year 2003.

**Table 1**

<b>Facility</b>	<b>Location</b>	<b>Type Equipment</b>	<b>Number of PET Procedures</b>
Baptist Memorial Hospital -Golden Triangle	Columbus	M	161
Baptist Memorial Hospital -North Mississippi	Oxford	M	257
North Mississippi Medical Center	Tupelo	M	175
<b>Total</b>			<b>593</b>

**Source:** Applications for Renewal of Hospital License for Calendar Year 2004 and FY 2003 Annual Hospital Report

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The applicant projects 251 PET procedures for the first year, and 318 for years two and three at the Grenada location.

The unit to be used for this proposed project (Insight Unit #G1258A) goes on a weekly basis to Jeff Anderson Regional Medical Center in Meridian, Singing River Hospital in Pascagoula, Memorial Hospital at Gulfport, and Thomas Hospital in Fairhope, Alabama. The unit goes to east Alabama Medical Center in Opelika, Alabama, every other week. Currently, the route is open every other Friday and every Saturday. Therefore, accommodating the proposed one day per month at GDR will not require a schedule change. According to the applicant, this unit performed 1,287 procedures from November 1, 2003 through October 31, 2004.

#### **SHP Criterion 2 - Registration**

The applicant requests approval to provide PET services at its facility through the utilization of a mobile PET scanner unit, which will be owned and operated by Insight, a mobile PET vendor. The applicant asserts that GDR and Insight Health Corporation are registered entities authorized to do business in Mississippi.

#### **SHP Criterion 4 - Assurance**

GDR asserts that it will comply with this criterion.

#### **SHP Criterion 5 - Approval From Radiological Health**

Grenada Diagnostic Radiology, LLC indicates that it will seek and receive the required approval before services begin.

#### **SHP Criterion 6 - Availability of Equipment**

GDR and/or Insight Health Corporation will have access to all necessary cyclotron-produced radiopharmaceuticals from an off-site medical cyclotron and a radiopharmaceutical production facility within a two hour air transport radius.

#### **SHP Criterion 7 - FDA Approval**

According to GDR, the mobile PET unit to be used by Insight Health Corporation has been approved by the FDA.

#### **SHP Criterion 8 - Staffing Availability**

According to the applicant, GDR will have a radiologist available for the PET unit to supervise performance and interpretation of PET scans. The radiologist, or a qualified associate, will be available during performance of the PET exams performed at GDR.

The applicant asserts that radiopharmaceuticals will be used that are manufactured at remote cyclotrons and available within a two hour air transport radius. A radiochemist and radiopharmacist will not be necessary on site. Insight Health Corporation will be responsible for contracting a physicist and appropriate engineers to maintain its equipment.

According to GDR, the facility has personnel in house who are designated to oversee all safety procedures and concerns of the proposed project. Insight Health Corporation, the vendor, asserts that it is responsible for supplying a registered nuclear medicine technologist specialized in PET during the hours of operation for the proposed project.

The applicant asserts that GDR has all other necessary personnel to oversee the operation of the scanner. These include a nurse, administrative and front desk personnel for the proposed project.

**SHP Criterion 9 - Medical Emergencies**

According to applicant, GDR has on-site the necessary equipment to handle a medical emergency in the PET scanner. These include a crash cart with appropriate life saving medications and equipment as well as a life-pak 12 resuscitation system. These are available within a few moments notice. During performance of a PET scan, if a medical emergency arises, the technologist will immediately notify the nurse and supervising physician at GDR. They will then oversee the emergency. If further medical care is needed, the applicant states that Grenada Medical Center is available through the use of their ambulance services less than 5 minutes away.

**SHP Criterion 10 - Referral System**

GDR affirms that it will comply with this criterion.

**SHP Criterion 11 - Established Protocols**

The applicant affirms that it will comply with this criterion.

**SHP Criterion 12 - Maintenance of PET Procedures**

The applicant indicates that GDR will comply with this criterion.

**SHP Criterion 13 - Maintenance of Required Data**

The applicant affirms that it will comply with this criterion.

**SHP Criterion 14 - Contracts**

Grenada Diagnostic Radiology, LLC included a copy of the contract in the application.

**SHP Criterion 15 - CON Exemption/Approval**

The applicant's vendor, Insight Health Corporation has two CONs (CON #R-0494 and CON #R-0495) to control mobile PET scanner equipment.

**B. General Review (GR) Criteria**

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Chapter 8 of the **Mississippi Certificate of Need Review Manual**, 2000 revisions, addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with applicable general review criteria.

**GR Criterion 2 - Long Range Plan**

According to the applicant, GDR plans to be a full service outpatient diagnostic imaging facility. The ability to offer PET services will further GDR's goal. Currently, GDR has patients who either have to go elsewhere to have these services, or go without. The applicant has seen increasing requests from its patients and referring physicians for PET services.

**GR Criterion 3 - Availability of Alternatives**

The applicant considered purchasing a PET scanner unit, however, this alternative was rejected. Leasing the services of a mobile PET scanner already operating in Mississippi was considered to be a much more efficient use of available resources.

**GR Criterion 4 - Economic Viability**

Based on the applicant's financial projections, this project appears to be economically viable with net incomes of \$240,341, \$319,095, and \$319,095 the first, second and third years, respectively.

Grenada Diagnostic Radiology's three year projected operating statement indicates that the facility is capable of undertaking the financial obligation of the proposed project.

**GR Criterion 5 - Need for Project**

The applicant indicates that GDR will provide services to and will not discriminate against those patients having low income, racial and ethnic minorities, women, handicapped persons and other under-served groups, or the elderly.

According to the applicant, the objective of the proposed project is to provide the citizens of Grenada County and neighboring communities with timely and convenient PET services. The facility will operate the PET services only one day per month.

The applicant believes that because the medical demands of the citizens of this community continue to rise, the proposed facility will help meet patient need and will facilitate the overall well-being of patients in the area.

The applicant asserts that Insight Health Corporation has two machines operating in Mississippi. The unit to be used for this proposal (Insight unit #G1258A) goes on a weekly basis to Jeff Anderson Regional Medical Center in Meridian, Singing River Hospital in Pascagoula, Memorial Hospital at Gulfport, and Thomas Hospital in Fairhope, Alabama. Further, this unit goes to east Alabama Medical Center in Opelika, Alabama every other week. Currently, the route is open every other Friday and every Saturday. Therefore, accommodating the proposed one day per month at GDR will not require a schedule change. This unit performed 1,287 procedures from November 1, 2003 through October 31, 2004.

The applicant submitted copies of affidavits from seven physicians indicating that they will refer 245 PET procedures the first year of operation. The application contains a letter of support/comments from one area physician for the proposed project.

**GR Criterion 6 - Access to the Facility or Service**

Grenada Diagnostic Radiology, LLC does not discriminate against and will provide access to the poor, physically handicapped, women, elderly, or members of racial and ethnic minorities.

According to the applicant, GDR projects that approximately 1 percent of its anticipated load of patients for the first year of operations, or approximately 1 patient, will be medically indigent.

**GR Criterion 7 - Information Requirement**

The applicant affirms that it will record and maintain the requested information and make it available to the Mississippi State Department of Health within 15 days of request.

**GR Criterion 8 - Relationship to Existing Health Care System**

Currently, North Mississippi Medical Center, Tupelo, Baptist Memorial Hospital - Golden Triangle, and Baptist Memorial Hospital - North Mississippi are the facilities authorized for mobile PET services in General Hospital Service Area 1. These facilities performed a total of 593 PET procedures for FY 2003. See table 1 of this staff analysis. GDR proposes to join a mobile route operated by Insight Health Corporation. The applicant intends to provide the citizens of Grenada and neighboring communities with timely and convenient PET services. The applicant believes that the proposed project is not expected to have an adverse impact on existing service providers in GHSA 1.

**GR Criterion 9 - Availability of Resources**

The applicant indicates that the proposed mobile PET services will be provided by Insight Health Corporation. GDR will provide the necessary radiologists to interpret the scans. All necessary radiology technicians will be provided under contract from Insight Health Corp., which will also provide the mobile PET equipment. Grenada Diagnostic Radiology, LLC also states that Dr. Ralph Armstrong, the managing member of GDR, will insure that the PET services are properly implemented.

**GR Criterion 10 - Relationship to Ancillary or Support Services**

According to the applicant, there will be no adverse effect on ancillary or support services.

**GR Criterion 16 - Quality of Care**

The applicant states that GDR provides high quality radiology services to the citizens of Grenada and Grenada County. The staff at GDR provides personal attention to each patient at GDR. The goal of GDR is to maintain radiology centered on the patient.

**IV. FINANCIAL FEASIBILITY**

A. Capital Expenditure Summary

Construction Cost	\$ 9,877.76
Site Preparation Cost	\$ 6,663.56
<b>Total Proposed Capital Expenditure</b>	<b>\$16,541.32</b>

The above capital expenditure is proposed to construct the concrete pad for the mobile PET scanner unit and for electrical wiring to support the unit at Grenada Diagnostic Radiology, LLC.

B. Method of Financing

The proposed capital expenditure of \$16,541.32 will be financed from GDR's accumulated cash reserves.

The applicant's three year projected operating statement indicates that Grenada Diagnostic Radiology, LLC is capable of undertaking the financial obligation of the proposed project.

C. Effect on Operating Cost

The applicant projects the following expenses, utilization and results from operation for the first three years following completion of this proposed project:

**Expenses**

Item	First Year	Second Year	Third Year
Supplies	\$ 82,830	\$104,940	\$104,940
Utilities	\$ 1,250	\$ 1,590	\$ 1,590
Depreciation	\$ 5,514	\$ 5,514	\$ 5,514
Lease Cost (PET Scanner)	\$ 49,200	\$ 49,200	\$ 49,200
<b>Total Expenses</b>	<b>\$138,794</b>	<b>\$161,244</b>	<b>\$161,244</b>

**Revenue**

Total Gross Rev.	\$ 715,350	\$ 906,300	\$906,300
Deductions	\$ (336,215)	\$(425,961)	\$(425,961)
Net Pt. Rev.	\$ 379,135	\$ 480,339	\$ 480,339
<b>Net Income (Loss)</b>	<b>\$ 240,341</b>	<b>\$ 319,095</b>	<b>\$ 319,095</b>

**Projected PET Procedures**

Number of Patients	251	318	318
Number of Procedures	251	318	318
Cost/Per Procedure	\$552.96	\$507.06	\$507.06
Charge/Per Procedures	\$2,850	\$2,850	\$2,850

D. Cost to Medicaid/Medicare

Payor Mix	Utilization Percentage	First Year Cost
Medicare	45	\$ 62,457
Medicaid	0	0
Other Payors*	55	\$ 76,337
<b>Total</b>	<b>100</b>	<b>\$138,794</b>

\*The applicant projects 3 percent of gross patient revenues to be provided to bad debt, 1 percent to charity care and 1 percent to medically indigent patients for the first three years of the proposed project.

V. **RECOMMENDATIONS OF OTHER AFFECTED AGENCIES**

The Division of Medicaid was provided a copy of the proposed application for review. The Division of Medicaid took no position on this project.

VI. **CONCLUSION AND RECOMMENDATION**

The project is in substantial compliance with the criteria and standards for the acquisition or otherwise control of a positron emission tomography (PET) scanner and related equipment/ services, as contained in the **FY 2005 State Health Plan**; Chapter 8 of the **Certificate of Need Review Manual**, 2000 revisions; and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

The Division of Health Planning and Resource Development recommends approval of this application submitted by Grenada Diagnostic Radiology, LLC.